UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,571	11/28/2000	John P. Anderson	015270-006444US	6100

21835 7590 01/17/2002

ELAN PHARMACEUTICALS, INC.
INTELLECTUAL PROPERTY DEPARTMENT
800 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,571	ANDERSON ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-131* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1-53, drawn to a β-secretase enzyme protein, classified in class 530 subclass 300 and 350, for example.

II. Claims 54-55, drawn to an antibody, classified in class 530, subclass 387.1, for example.

III. Claims 56-77, drawn to a isolated nucleic acid, expression vectors, host cells and methods of producing a polypeptide using the vectors and host cells, classified in class 435, subclass 69.1, 320.1, and 455, for example.

IV. Claims 78-80, 84-85, drawn to a method for screening undisclosed compounds for inhibition of Aβ production in cells, unclassifiable due to lack of specific identification of compounds.

V. Claims 78, 81-85, drawn to a method for screening undisclosed compounds for inhibition of Aβ production in a mammalian subject, unclassifiable, due to lack of specific identification of compounds.

VI. Claims 86-90, drawn to a method of screening compounds that inhibit Aβ production using an inhibitor, classified in class 435, subclass 4, for example.

VII. Claims 91-99, drawn to undisclosed β-secretase inhibitor compounds, unclassifiable.

VIII. Claims 91-103, drawn to a β-secretase inhibitor compound, wherein the inhibitor is a peptide, classified in class 530, subclasses 300 and 350, for example.

IX. Claims 104-107, drawn to a screening kit containing an isolated β-secretase protein, and a cleavable β-secretase substrate, classified in class 530, subclasses 300 and 350, for example.

X. Claims 108-111, drawn to a knockout mouse, classified in class 800, subclass 18, for example.

XI. Claims 112-113, drawn to a method of screening for drugs for treatment of Alzheimer's disease using a mammalian subject, classified in class 424, subclass 9.2 and class 800, subclass 3, for example.

XII. Claims 114-120, drawn to methods of treating a patient by administration of undisclosed inhibitors, and inhibiting enzymatic proteolysis, unclassifiable.

XIII. Claims 114-120, drawn to methods of treating a patient by administration of a inhibitor, wherein the inhibitor is a peptide, and inhibiting enzymatic proteolysis, classified in class 514, subclass 2, for example.

XIV. Claims 121-126, drawn to a method of diagnosing Alzheimer's disease in a patient, by detection of gene expression, classified in class 435, subclass 6.

XV. Claims 127, drawn to a method of purifying a β-secretase protein enzyme molecule using undisclosed β-secretase inhibitors, classified in class 435, subclass 7.1, for example.

XVI. Claims 127-131, drawn to a method of purifying a β-secretase protein enzyme molecule using a β-secretase inhibitor, wherein the inhibitor is a peptide, classified in class 435, subclass 7.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX, XII-XVI are distinct, each from each other because of the following reasons: the peptides in Inventions I, VIII, IX, XIII and XVI are distinct in chemical structure and function, as well as therapeutic function from the antibody in Invention II, the nucleic acid in Inventions III and XIV, and the undisclosed

inhibitors in Inventions IV-VII, XII and XV. Additionally, peptides, antibodies, nucleic acids and inhibitors can be used in materially different methods. For example, polypeptides can be used for antigen presenting cell priming, antibodies can be used in screening assays, and nucleic acids can be used as detection probes.

Invention I is distinct from Invention VIII, XIII and XVI, because the β-secretase protein in Invention I has distinct chemical structure and function, as well as therapeutic function from the β-secretase inhibitors in Inventions VIII, XIII, and XVI.

Invention I and Inventions IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the β-secretase enzyme protein in Invention I can be used in a materially different process than the screening kit of Invention IX, for example, in the production of antibodies.

Inventions VIII, XIII and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case, the inhibitor of Invention VIII can be used in a materially different process from the methods of treatment in Invention XIII and the method of protein purification in Invention XVI, such as an *in vitro* inhibition assay. Additionally, the methods of purifying a protein in Invention XVI require different technical considerations and different modes of actions than treatment of a patient by administration of an inhibitor in Invention XIII.

The inhibitors in Inventions IV- VII, XII, and XV are undisclosed, therefore, a search for this group would be considered an undue search burden.

Invention III and Invention XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids in Invention III can be used in a materially different process, such as detection probes, from the methods of diagnosing Alzheimer's disease in a patient by the detection of gene expression.

Inventions I-IX, XII-XVI and Inventions X and XI are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operations, different functions and different technical considerations. The

generation of the knock-out mouse of Invention X and the method of screening in Invention XI require different technical considerations and different modes of action than the peptides, antibodies, nucleic acids, and inhibitors in Inventions I-IX, XII-XVI.

Invention X is unrelated to Invention XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operations, different functions and different technical considerations. The knock-out mouse of Invention X requires different technical considerations and different modes of action than methods for screening for drugs effective for the treatment of Alzheimer's comprising administering a β-secretase inhibitor to a mammalian subject which reduces the amount of Aβ deposition in the subject or improves cognitive ability.

The inventions above have acquired a separate status in the art as a separate subject for inventive effort and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Sequence Election Requirement Applicable to All Groups

In addition, some of the claims detailed above read on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to the sequences. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect up to 10 nucleic acid sequences (See MPEP 803.04).

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single

application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Although the MPEP deems that up to ten nucleotide sequences may be searched without restriction, it has recently been decided by the Director of Biotechnology at the USPTO that searching more than one sequence per application will place an undue burden upon the Examiner and the Office. For this reason, restriction to ONE SEQUENCE is being applied to all applications at this time.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Clark, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800~~1630~~

TNT

Thaian N. Ton
Patent Examiner
Group 1632